

REMARKS

This Amendment is submitted in reply to the final Office Action dated July 8, 2009. A petition for a one-month extension of time is submitted herewith. The Director is authorized to charge the amount of \$130.00 for the cost of the one-month extension of time, and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00737 on the account statement.

Claims 1-9, 11-16, 19-20 and 23-24 are pending in this application. Claims 1-8 and 19-20 were previously withdrawn from consideration, and Claims 10, 17-18, 21-22 and 25-26 were previously canceled without prejudice or disclaimer. In the Office Action, Claims 9 and 11-15 are rejected under 35 U.S.C. §112. Claims 9, 11-15 and 23-24 are rejected under 35 U.S.C. §102. In response, Claims 9, 13, 16 and 23-24 have been amended, Claim 15 canceled and Claim 27 newly added. The amendments do not add new matter. The new claim does not add new matter. At least in view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

Applicants note that Claims 13 and 24 have been amended solely for clarification purposes. These amendments do not add new matter. The amendments are supported in the Specification at, for example, page 1, paragraph 13; page 2, paragraph 20; page 3, paragraphs 36-37 and 40-41; page 4, paragraph 42; page 5, paragraphs 82-84.

In the Office Action, Claims 9 and 11-15 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Patent Office asserts that the term "improving" is indefinite because it is subject to interpretation. See, Office Action, page 3, lines 1-2. In response, Applicants have amended Claim 9 to recite "a method for improving at least one skin characteristic of a human or pet animal, wherein the at least one skin characteristic is selected from the group consisting of photoprotection, hydration, dryness, firmness, elasticity, oiliness, thickness, regular pigmentation, barrier function, antioxidant status, reduced risks of cancer or inflammation, modulated sebum production or composition, and reduced signs of ageing in the elderly." This amendment does not add new matter. The amendment is supported in the Specification at, for example, page 1, paragraph 11; page 2, paragraph 28; pages 2-3, paragraph 29; page 3, paragraph 30; page 5, paragraph 84. Applicants respectfully submit that one of

ordinary skill in the art would understand that improving the specific skin characteristics now recited is quantifiable and not subject to interpretation. For example, one of ordinary skill in the art would understand that improving the firmness of skin means making the skin firmer, whereas improving the dryness of skin means making the skin less dry. Moreover, the Specification teaches that the effect of the claimed compositions on skin of humans or pets “can be measured by using conventional methods including minimal erythema dose (MED), colorimetry, transepidermal water loss, DNA repair [], measure of interleukins and proteoglycans production, or collagenase activity, barrier function or cell renewal.” See, Specification, page 3, paragraph 30. Thus, one of ordinary skill in the art would understand that a method for improving one of the specific skin characteristics now recited is quantifiable rather than subject to interpretation and, thus, Claim 9 is not indefinite.

Accordingly, Applicants respectfully request that the rejection of Claims 9 and 11-15 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 9, 11-15 and 23-24 are rejected under 35 U.S.C. §102(b) as being anticipated by Clinical Pharmacology & Therapeutics, July 1996, 60(1): 34-40 to Ameer et al. (“*Ameer*”) as evidenced by the Hesperidin 170 article (“*Hesperidin 170*”). In response, Claim 9 has been amended and Claim 15 canceled. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that *Ameer* fails to disclose every element of the present claims.

Currently amended independent Claim 9 recites, in part, a method for improving at least one skin characteristic of a human or pet animal, wherein the at least one skin characteristic is selected from the group consisting of photoprotection, hydration, dryness, firmness, elasticity, oiliness, thickness, regular pigmentation, barrier function, antioxidant status, reduced risks of cancer or inflammation, modulated sebum production or composition, and reduced signs of ageing in the elderly, the method comprising the step of orally administering a composition comprising a therapeutically-effective amount of at least one flavanone compound as an active ingredient to a human or pet animal requiring improvement in the at least one skin characteristic.

Similarly, currently amended independent Claim 23 recites, in part, a method for treating a disorder selected from the group consisting of disorders of the skin, hair and coat comprising the step of orally administering to an individual having a disorder of the skin, hair or coat a

composition comprising a therapeutically-effective amount of, as an active ingredient, at least one flavanone compound to treat the skin, hair and/or coat disorders. These amendments do not add new matter. The amendments are supported in the Specification at, for example, page 1, paragraphs 4 and 11; page 2, paragraphs 20, 22 and 28; pages 2-3, paragraph 29; page 3, paragraph 30; page 5, paragraph 84. By administering a therapeutically effective amount of the claimed flavanone compounds as an active ingredient to an individual requiring improvement in specific skin characteristics or suffering from skin, hair or coat disorders, the claimed method can be used to improve specific skin characteristics and treat the skin, hair or coat disorders of the individual. See, Specification, page 1, paragraphs 7-12. In contrast, *Ameer* fails to disclose every element of the present claims.

For example, *Ameer* fails to disclose or suggest orally administering a composition comprising a therapeutically-effective amount of at least one flavanone compound as an active ingredient to a human or pet animal requiring improvement in the at least one skin characteristic as required, in part, by independent Claim 9. The Patent Office admits that *Ameer* fails to specifically teach using hesperidin to prevent skin disorders but nevertheless asserts that *Ameer* inherently teaches the claimed method “because both the reference and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has skin. . . [and] on the administration of hesperidin to any patient, a prevention of skin disorder would have had to occur.” See, Office Action, page 3, lines 17-21; page 4, lines 1-2. However, the present claims do not recite administering hesperidin to any patient in order to prevent skin disorders but rather administering the composition to a specific patient that requires improvement in the skin characteristics. Contrary to the Patent Office’s assertion, *Ameer* fails to disclose administering its composition to the same patient as the present claims. Although Applicants acknowledge that every person has skin, not every human or pet animal requires improvement in one of the claimed skin characteristics.

Ameer is entirely directed to testing the absorption of flavanones after hesperidin and citrus administration. See, *Ameer*, Title; page 34, paragraph 3; page 37, paragraph 7. *Ameer* merely discloses administering its compounds to a 25-year-old white man who “was healthy, within 10% of his ideal body weight, [] was taking no medication[, and] did not smoke tobacco or drink alcohol,” as well as “[t]hree additional adults between the ages of 25 and 87.” See,

Ameer, page 34, paragraph 4. Nowhere does *Ameer* disclose administering its composition to an individual requiring improvement in one of the claimed skin characteristics, nor does the Patent Office cite support for such claimed element. In fact, because *Ameer* states that its study “is the first report to document oral absorption in humans of the citrus flavanones naringenin and hesperidin,” Applicants respectfully submit that *Ameer* would not have suggested administering hesperidin to individuals to treat skin disorders or improve the claimed skin characteristics. See, *Ameer*, page 37, paragraph 7. Thus, *Ameer* fails to disclose orally administering a composition comprising a therapeutically-effective amount of at least one flavanone compound as an active ingredient to a human or pet animal requiring improvement in the at least one skin characteristic as required, in part, by independent Claim 9 and Claims 11-15 that depend therefrom.

For at least substantially the same reasons as discussed above, Applicants respectfully submit that *Ameer* fails to disclose orally administering to an individual having a disorder of the skin, hair or coat a composition comprising a therapeutically-effective amount of, as an active ingredient, at least one flavanone compound to treat the skin, hair and/or coat disorders as required, in part, by independent Claim 23 and Claim 24 that depends therefrom. Specifically, *Ameer* is entirely directed to testing the absorption of flavanones after hesperidin and citrus administration and fails to teach or even suggest administering its composition to an individual having a disorder of the skin, hair or coat. See, *Ameer*, Title; page 34, paragraph 3; page 37, paragraph 7.

Accordingly, Applicants respectfully request that the rejection of Claims 9, 11-15 and 23-24 under 35 U.S.C. §102(b) to *Ameer* as evidenced by *Hesperidin 170* be withdrawn.

In the Office Action, Claims 9, 11-12, 14-15 and 23-24 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,049,798 to Bottomley (“*Bottomley*”) as evidenced by *Hesperidin 170*. In response, Claims 9 and 23 have been amended and Claim 15 canceled. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that *Bottomley* fails to disclose every element of the present claims.

For example, *Bottomley* fails to disclose or suggest orally administering at least one flavanone compound selected from the group consisting of isosacuranetin, naringin, hesperidin, eriodictyol, poncirin, neoeriocitrin or a derivative of at least one flavanone selected from the group consisting of their aglycone, chalcone, glycosylated or methylated forms and sulfated and

glucuronidated forms which are a product of their metabolism in blood, or a mixture thereof as required, in part, by independent Claims 9 and 23. The Patent Office asserts that *Bottomley* discloses a method for treatment of herpes simplex with a mixture of vitamin C and vitamin P and that hesperidin is known as vitamin P. See, Office Action, page 4, lines 17-21; page 4, lines 1-2. However, the *Hesperidin 170* reference relied on by the Patent Office expressly states that hesperidin is “no longer referred to, except in older literature, as vitamin P.” See, *Hesperidin 170*, page 1, paragraph 2. *Hesperidin 170* fails to teach how old the “older literature” is and which specific “older literature” refers to hesperidin as vitamin P. Although *Bottomley* was issued in 1977, *Hesperidin 170* fails to disclose whether *Bottomley* was “older literature” that referred to hesperidin as vitamin P or whether the “vitamin P” in *Bottomley* was used in the current way such that hesperidin was not included. Nowhere does *Bottomley* disclose or even use the term “hesperidin.” As such, Applicants respectfully submit that *Bottomley* fails to disclose or suggest orally administering at least one flavanone compound selected from the group consisting of isosacuranetin, naringin, hesperidin, eriodictyol, poncirin, neoeriocitrin or a derivative of at least one flavanone selected from the group consisting of their aglycone, chalcone, glycosylated or methylated forms and sulfated and glucuronidated forms which are a product of their metabolism in blood, or a mixture thereof in accordance with the present claims.

Moreover, *Bottomley* fails to disclose administering a composition comprising a therapeutically-effective amount of, as an active ingredient, at least one claimed flavanone compound or a claimed derivative of at least one flavanone as required, in part, by independent Claims 9 and 23. *Bottomley* is entirely directed to treating herpes simplex with a mixture of vitamin C and vitamin P. See, *Bottomley*, Title; Abstract; column 3, lines 21-30. Nowhere does *Bottomley* disclose treating herpes simplex with one of the specifically claimed flavanone compounds as an active ingredient. In fact, because *Bottomley* never uses the term “hesperidin,” it is unclear how much hesperidin, if any, is contained in its vitamin P. Therefore, Applicants respectfully submit that *Bottomley* fails to describe administering a therapeutically effective amount of one of the claimed flavanone compounds as required, in part, by the present claims.

Accordingly, Applicants respectfully request that the rejection of Claims 9, 11-12, 14-15 and 23-24 under 35 U.S.C. §102(b) to *Bottomley* as evidenced by *Hesperidin 170* be withdrawn.

In the Office Action, Claims 9 and 16 are rejected under 35 U.S.C. §102(b) as being anticipated by Japanese Patent Publication No. 09-252746 to Mizuguchi ("*Mizuguchi*"). In response, Claims 9 and 16 have been amended. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that *Mizuguchi* fails to disclose every element of the present claims.

For example, *Mizuguchi* fails to disclose or suggest a method for improving at least one skin characteristic of a human or pet animal, wherein the at least one skin characteristic is selected from the group consisting of photoprotection, hydration, dryness, firmness, elasticity, oiliness, thickness, regular pigmentation, barrier function, antioxidant status, reduced risks of cancer or inflammation, modulated sebum production or composition, and reduced signs of ageing in the elderly as required, in part, by independent Claim 9. The Patent Office asserts that *Mizuguchi* teaches a food supplement to promote hair growth and prevent hair loss with a tablet of hesperidin. See, Office Action, page 5, lines 19-22. However, nowhere does *Mizuguchi* teach or suggest improving a skin characteristic selected from the group consisting of photoprotection, hydration, dryness, firmness, elasticity, oiliness, thickness, regular pigmentation, barrier function, antioxidant status, reduced risks of cancer or inflammation, modulated sebum production or composition, and reduced signs of ageing in the elderly, nor does the Patent Office cite support in *Mizuguchi* for such claimed elements. In fact, the skin characteristics recited in currently amended Claim 9 were previously included in Claim 15, yet the Patent Office asserted *Mizuguchi* only against Claims 9 and 16. See, Office Action, page 5, lines 17-18. As such, *Mizuguchi* fails to suggest a method for improving at least one skin characteristic of a human or pet animal, wherein the at least one skin characteristic is selected from the group consisting of photoprotection, hydration, dryness, firmness, elasticity, oiliness, thickness, regular pigmentation, barrier function, antioxidant status, reduced risks of cancer or inflammation, modulated sebum production or composition, and reduced signs of ageing in the elderly as required, in part, by Claims 9 and 16.

Moreover, *Mizuguchi* fails to disclose administering a composition comprising a therapeutically-effective amount of, as an active ingredient, at least one claimed flavanone compound or a claimed derivative of at least one flavanone as required, in part, by independent Claim 9. *Mizuguchi* is entirely directed to treating or preventing hair loss using a combination of

Taheebo extracts and a natural mineral. See, *Mizuguchi*, paragraphs 1-3. As such, the Taheebo extracts and natural mineral are the active ingredients in the compositions of *Mizuguchi*. Although *Mizuguchi* teaches that its composition may include hesperidin, nowhere does *Mizuguchi* disclose administering a therapeutically-effective amount of hesperidin as an active ingredient. See, *Mizuguchi*, paragraphs 4-5. In fact, *Mizuguchi* never discloses how much hesperidin is used in its composition. Therefore, Applicants respectfully submit that *Mizuguchi* fails to describe administering a therapeutically effective amount of one of the claimed flavanone compounds as required, in part, by the present claims.

Furthermore, Applicants note that Claim 16 has been amended to remove the reference to preventing hair and coat loss. This amendment does not add new matter. The amendment in supported in the Specification at, for example, page 1, paragraph 11; page 3, paragraph 29. As discussed previously, *Mizuguchi* is entirely directed to treating or preventing hair loss using a combination of Taheebo extracts and a natural mineral. See, *Mizuguchi*, paragraphs 1-3. Thus, *Mizuguchi* fails to disclose administering a composition to improve hair and coat gloss, hair density, color, oilness, to ameliorate hair fiber diameter, and sebum production as required, in part, by Claim 16.

Accordingly, Applicants respectfully request that the rejection of Claims 9 and 16 under 35 U.S.C. §102(b) to *Mizuguchi* be withdrawn.

Applicants further notes that Claim 27 has been newly added. The new Claim is fully supported in the Specification at, for example, page 5, paragraphs 82-84. No new matter has been added thereby. Applicants respectfully submit that the subject matter as defined in the newly added claims is patentable over the cited art for at least substantially the same reasons as discussed above.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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